UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,016	03/11/2004	Michel Gilbert	019633-000912US	7215

20350 7590 01/04/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,016	GILBERT ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/11/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-50* is/are rejected.

7)☒ Claim(s) *40 and 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 35-50 are pending.

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Removal of the hyperlink at page 9, line 22 is required.

Drawings

2. The Brief Description of the Drawings is incomplete for Figure 3 which shows two amino acid sequences which must be identified by sequence identifiers (SEQ ID NO). Insertion of the SEQ ID Nos for both sequences in the Brief Description of the Drawings is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 35-47 and 49-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6709834. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of alpha-2,3-sialyltransferase is encompassed by the instantly claimed invention, in light of the fact that the polypeptide of '834 was isolated from Campylobacter and has an amino acid sequence of 100% identity to the amino acid sequence of 1-328 or 1-430 of SEQ Id NO 2. The allowed species anticipates the instantly claimed genus of alpha-2-3-sialyltransferase polypeptides of SEQ ID NO 2 .

Claim Objections

5. Claim 40 is objected to because of the following informalities: Claim 40 recites the terms "myc, V-5 and FLAG"; the recitation of abbreviations in the claims is permitted upon their definition at their first appearance in the claims. The meaning of these terms should be set forth at their first appearance in the claims. Appropriate correction is required.

6. Claim 48 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend for other claims in the alternative and not multiple claims simultaneously. Claims 48 depends from both claim 41 and 37 simultaneously. See MPEP § 608.01(n). Accordingly, the claim 48 will not been further treated on the merits.

Claim Rejections - 35 U.S.C. § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Please Note: The **written description** rejection being made of record below is over claims which recite the phrase a polypeptide that comprises **an amino acid sequence** with"at least 90% identity to residues 1-328 of SEQ ID NO 2" .

8. Claims 35-47, 49-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 1-2 and therefore the written description is not commensurate in scope with the claims drawn to an isolated polypeptide molecule that only shares 90% identity with an amino acid sequence set forth as SEQ ID NOs: 2. The specification does not provide written descriptive support for the claimed invention of "at least 90%" identical to an amino acid sequence as set forth in SEQ ID NO 2 . Within the scope of the claimed invention of at least 90% identical to an amino acid sequence of SEQ ID NO 2 are sequences that are homologs, or allelic variants of SEQ ID No 1 and 2.

The specification on page 8, lines 21-page 12, line 10, on page 10, lines 20-32 it states that the claimed invention encompasses:

> "Another indication that two nucleic acid sequences are substantially identical is that the two molecules hybridize to each other under stringent conditions".

at page 14, the use of any cDNA library from any source is suggested for the isolation of a nucleic acid that would encode any sialyltransferase polypeptide:

"A nucleic acid encoding a sialyltransferase is isolated by routine cloning methods. A nucleotide sequence of a sialyltransferase-encoding gene or cDNA, as provided herein, is used to provide probes that specifically hybridize to a sialyltransferase cDNA in any cDNA library, a sialyltransferase gene in a genomic DNA sample, or to a sialyltransferase mRNA in a total RNA sample."

at page 15, lines 11-17 it is suggested that alterations of the disclosed sequences, to obtain a modified sialyltransferase polypeptide, are also within the scope of the invention and states:

" It may be desirable to modify the sialyltransferase nucleic acids of the invention. One of skill will recognize many ways of generating alterations in a given nucleic acid construct. Such well known methods include site directed mutagenesis, PCR amplification using degenerate oligonucleotides, exposure of cells containing the nucleic acid to mutagenic agents or radiation, chemical synthesis of a desired oligonucleotide". The instant specification suggests, but does not provide written descriptive support for the full scope of the invention that comprises a polypeptide sequence that is "at least about 75% identical to an amino acid sequence as set forth in SEQ ID NO 2" .

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:1 or 2, the skilled artisan cannot envision the detailed structure of the polypeptide or a recombinant polypeptide encoded by a polynucleotide and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a

genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Description of a single polypeptide based upon its amino acid sequence and biological activity does not describe, nor enable a highly variable genus of polypeptides that shares a common an amino acid sequence and a common biological function. While Figure 3 of the instant specification, shows a Haemophilus influenza amino acid sequence compared to the sequence of Campylobacter jejuni, the Haemophilus influenza amino acid sequence does not share 90% sequence identity over the entire length of SEQ Id NO 2, and therefore does not define an additional species in the instantly claimed genus nucleic acids that encode polypeptides with 90% sequence identity to amino acids 1-328 or 1-420.

The instantly claimed invention has not been so described by written description in order to enable the full scope of the invention because the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as well as the instant specification does not provide guidance, teaching and suggestion as to where changes can be made that would result in an alpha 2-3 sialyltransferase polypeptide.

However, no disclosure, beyond the mere mention of naturally occurring analogues (natural allelic variants or homologs) is made in the specification or the suggestion of the construction of mutant nucleic acid sequences. This is insufficient to support the generic claims

as provided by the Interim Written Description Guild lines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilbert et al (1996, Journal of Biological Chemistry, Reference of Record, Applicant's IDS submission).

The claimed invention is directed to an isolated α-2,3 sialyltransferase polypeptide, that shares at least 90% sequence identity with an amino acid sequence of any length in SEQ ID NO 2 (Instant claim 35) and must comprise 328 or 430 amino acids .

(Instant claim 35) Gilbert et al a recombinantly produced and isolated α-2,3 sialyltransferase polypeptide, that shares at least 90% sequence identity with an amino acid sequence of any length in SEQ ID NO 2 (see page 28274, col. 1, paragraph 3), the coding sequence being one that shares at least 90% sequence identity with an amino acid sequence of any length in SEQ ID NO

2 (an amino acid sequence of "LIV (figure 3, first line, top of col. 1, page 28274)" , wherein the amino acid sequence shares 100% sequence identity with SEQ ID NO 2 at amino acids 10-12.

The recombinant polypeptide was an α-2,3 sialyltransferase polypeptide of about 328 amino acids, specifically 304 amino acids (about 10 % variation), the sequence disclosed is a type of derivative of a Campylobacter jejuni polynucleotide sequence as both N.meningitidis and C.jejuni produce sialylated oligosaccharides (see page 28271, col 2, paragraph 1).

The instantly claimed α-2,3 sialyltransferase polypeptide is anticipated by Gilbert et al as now claimed. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

9. Claims 41-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Paulson et al (US Pat. 6,399,336; effective filing date January 16, 1997; reference of record; Applicant's IDS submission).

The claimed invention is directed to a method of adding a sialic acid residue to an acceptor molecule comprising a terminal galactose residue, the method comprising the steps of

contacting the acceptor molecule with an activated sialic acid molecule and an alpha 2,3 transferase that comprises an amino acid sequence held in common with SEQ ID No 2.

Paulson et al (US Pat. 6,399,336) disclose a method of adding a sialic acid residue to an acceptor molecule comprising a terminal galactose residue (see all claims, especially claims 3,19-20, 28, 50-51, 55,61-66, 80-81, col. 3, lines 19-38; col. 8, lines 42-52; col. 9, lines 12-33; col. 11, lines 17-43; Tables 3 and 4, Example III, col. 16), the method comprising the steps of :

contacting the acceptor molecule with an activated sialic acid molecule and an alpha 2,3 transferase that comprises an amino acid sequence held in common with SEQ ID No 2. Paulson et al. Disclose and show a method of adding sialic acid to an acceptor sugar using a genus of C.jejuni alpha-2-3 sialyltransferase enzymes. Paulson et al named the enzymes used in the claimed methods, specifically sialyltransferase enzymes (see Table 4, col. 16, lines 30-40, specifically ST3Gal VI; also see all claims, especially claims 3,19-20, 28, 50-51, 55,61-66, 80-81, col. 3, lines 19-38; col. 8, lines 42-52; col. 9, lines 12-33; col. 11, lines 17-43; Tables 3 and 4, Example III, col. 16) and specifically a C.jejuni alpha-2-3 sialyltransferase enzyme.

With respect to additional description of molecules, they were described with respect to the pathogen from which the sialyltransferase was obtained, the specific molecule transferred, the type of bond linkage formed upon transfer and sequences were incorporates by reference to various articles. Inherently the method of adding a sialic acid residue to an acceptor molecule which utilizes a Campylobacter jejuni 2,3 sialyltransferase would share at least 90% sequence identity to an amino acid sequence with residues 1-328 of SEQ ID No 2, as the source of the sialyltransferase is identical and evidences the identical biological activity.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or

of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. US006503744B1 is cited to show nucleic acid sequences for two heptosyl transferases for Campylobacter jejuni.

12. US Pat. 6699705; and 6210933 (Gilbert et al) are cited to s how sialyltransferases.

13. Gilbert et al (US Pat. 6,096,529) is cited to show recombinant sialyltransferases.

14. Sasaki et al (1996, US Pat. 5,494,790) is cited to show an α-2,3 sialyltransferase polypeptide, the sequence being one that shares at least 90% sequence identity with an amino acid sequence of any length in SEQ ID NO 2.Sasaki et al disclose a recombinantly produced polypeptide encoded by a polynucleotide sequence the encodes an α-2,3 sialyltransferase polypeptide (see Example 3, col. 26, lines 36-59, col. 40, lines 25-30). The polypeptide encoded by the polynucleotide sequence shares at least 75% sequence identity with an amino acid sequence of any length in SEQ ID NO 2 , specifically the amino acid sequence of "FPF" is found to be encoded by SEQ ID No 5(NA) and in the amino acid sequence of SEQ ID NO 7 (AA)(see of SEQ ID NO 5 or SEQ ID 7 at locations corresponding to amino acids 31-33; amino acids 35-37 of SEQ ID NO 1(NA)/SEQ ID No 2(AA))" shares 100% sequence identity with instant SEQ

ID NO 2 at amino acids 48-50). The α-2,3 sialyltransferase polypeptide was of about 328 amino acids, specifically 329 or 333 amino acids (see sequence listing pages of Sasaki et al).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
December 15, 2005

MARK NAVARRO
PRIMARY EXAMINER